

### **REMARKS**

We note that the rejection of claims 1, 3-8, and 10-11 has been expressly withdrawn and these claims stand allowed. (Paper No. 16 at 2 and 5.)

#### **Rejection under 35 USC § 102**

Claims 22-24 and 26-34 were rejected under 35 USC § 102(b) as anticipated by Schmidt et al., U.S. Patent No. 4,605,666 ("Schmidt"). (Paper No. 16 at 2.)

For the reasons set forth below, the rejection respectfully is traversed.

Schmidt discloses a powder containing a water-soluble vitamin prepared by spray drying an aqueous slurry of the vitamin, a binder, a lubricant, and optionally an adsorbent and an additional excipient. (Col. 1, line 52 - col. 2, line 54).

In making the rejection, the Examiner asserted that Schmidt discloses "a powder or tablet composition, comprising a water-soluble vitamin (i.e., sodium ascorbate, ascorbic acid); a binder (i.e., microcrystalline cellulose); a lubricant (i.e., stearic acid, magnesium stearate, calcium stearate) and an excipient (i.e., pectin, starch), wherein the final powder formed will contain at least 80% (preferably at least 90) percent by weight of the water soluble vitamin, less than 15 (preferably less than 9) percent by weight of binder ... 0.2 to 5 percent by weight of the lubricant and less than 3 percent of other excipients." (Paper No. 16 at 3.) The Examiner then summarily concluded that "[o]ne of ordinary skill in the art is able to 'at once envisage' the claimed composition within the sufficiently limited or well-delineated components and their dosage ranges, the composition is anticipated." (*Id.*)

The Examiner, however, acknowledged that "Schmidt is silent about the functional characteristic of using pectin as a binder..." (*Id.*) To fill this acknowledged gap, the Examiner asserted that "the functional characteristic of using pectin as a binder ... must be inherent to the pectin. Therefore, the claimed composition is still properly rejected by a [cited document], even if the [cited document] does not address or acknowledge the property." (*Id.*)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). And, the Examiner must show that there is no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

Initially, we note that the Examiner has previously expressly conceded that Schmidt does not anticipate the composition of claims 22-34. In the Office Action dated February 5, 2003, the Examiner rejected claims 1-13 and 22-34 solely under 35 U.S.C. 103(a) over Schmidt and if necessary, further view of Newlin, U.S. Patent No. 3,615,591 ("Newlin"), Chiralt et al., 1999 IFT Annual Meeting ("Chiralt"), and Hussaini et al., A Guide to Halal food Selection 1993 ("Hussaini"). (Paper No. 11 at 3.) The Examiner stated only that "[t]his rejection is analogous to the original rejection" found in the Office Action dated June 26, 2002. (*Id. citing* Paper No. 9.)

In Paper No. 9, the Examiner acknowledged that "***Schmidt differs from the claimed invention in*** 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt; 3) the use of citrus pectin; and 4) the functional characteristic of pectin as a binder." (Paper No. 9 at 4; See also, Paper No. 3 at 4.)

The claims have not changed since Paper No. 11, nor has Schmidt changed. Nor has the Examiner explained the apparent discrepancy between Paper Nos. 9 and 11 and the present Office Action. Thus, the record reflects an unambiguous admission that there are at least four differences between claims 22-24 and 26-34 and Schmidt. For this reason alone, the rejection should be withdrawn.

If the PTO desired to assert a § 102 rejection of claims 22-24 and 26-34 based on Schmidt, the time to have done so was in Paper No. 11 – the Office Action following the September 22, 2002 Response presenting those claims. The § 102 rejection is nothing more than a belated attempt to rewrite the history of this prosecution, which spans three years. This rejection is contrary to the PTO's stated policies and is a text book example of piecemeal prosecution clearly frowned upon by the PTO. "Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references." MPEP 707.07(g) (8<sup>th</sup> Ed., Rev. 1, February 2003, p. 700-116.) For this reason also, the rejection should be withdrawn.

Notwithstanding the foregoing, the rejection falls short factually. Specifically, the rejection fails to identify where Schmidt discloses a "composition

having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder,” as claimed. Apparently acknowledging this shortfall, the Examiner seeks refuge in the “inherent” properties or characteristics of pectin. (Paper No. 16 at 4.) It is, however, the claimed composition for which the Examiner must demonstrate “identity of invention” with the disclosure of Schmidt. Whatever the inherent properties of pectin may be, simply stated, pectin is not the claimed composition.

In discussing this “property or characteristic” of pectin the Examiner has failed to demonstrate that Schmidt discloses “each and every element” of the **claimed composition**, namely “a composition having a compressibility superior to a composition comprising ... a standard binder.” Not one of the exemplified embodiments of Schmidt discloses the use of pectin as a binder. (Col 3, line 27 - col. 6, line 53; Examples 1-5 and comparison example.) Not one of the exemplified embodiments of Schmidt discloses the use of pectin even as an excipient. (*Id.*) In fact, pectin is disclosed simply as one of twelve identified carbohydrates, which are non-preferred excipients that may be present in an amount “less than three percent.” (See Col. 2, lines 45-66.)

For the reasons set forth above, the rejection fails to disclose where in Schmidt each and every element of claims 22-24 and 26-34 are suggested, let alone disclosed. Thus, the rejection fails to set forth a *prima facie* case of anticipation. Nor would the rejection be sufficient to support a *prima facie* case of obviousness. Accordingly, the rejection should be withdrawn.

**Rejection under 35 USC § 103**

Claim 25 was rejected under 35 USC § 103(a) as being unpatentable over Schmidt in view of Hill, U.S. Patent No. 3,946,110 ("Hill"). (Paper No. 16 at 5.)

For the reasons set forth below the rejection, respectfully is traversed.

Schmidt is summarized above.

Hill discloses "improvements in analgesic and antifebrile or antipyretic compositions ... by compounding them with natural, water-swellaable gums, preferably those having a poly-uronic acid molecular structure such as pectins and alginates of various origins, tragacanth, karaya, and other gums such as carrageenin." (Col. 1, line 11 - col. 2, line 1.) Hill discloses the use of citrus pectins at, for example, column 4, lines 46-50 and Example 1, column 8, line 43.

In making the rejection, the Examiner relied solely on the characterization of Schmidt found in the § 102 rejection. (Paper No. 16 at 5.) The Examiner acknowledged, however, that Schmidt differs from the presently claimed invention "in the use of citrus pectin in said composition." (*Id.*) To remedy this acknowledged gap, the Examiner relied upon Hill as disclosing "the use of pectin, namely citrus pectin, in preparing medicinal tablet composition (Examples 9-16)." (*Id.*) The Examiner also asserted that Hill discloses "that pectins are commonly found in edible fruits and vegetables, including apples and citrus fruits, and are generally isolated from them." (*Id.*) The Examiner then concluded that "[t]o incorporate such teaching into the teaching of Schmidt, would have been obvious in view of Hill ...." (*Id.*)

To further bolster the rejection the Examiner asserted that "[o]ne having ordinary skill in the art would have expected in view of Hill that citrus pectin would be

preferred in preparing pharmaceutical tablet composition, maybe due to its lighter color than other source of pectins. Furthermore, one ... would have been motivated to modify [Schmidt] with the reasonable expectation of success, such that said composition can be readily formed into tablet when it is compressed." (*Id.*)

As is well settled, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

Initially we note that the rejection uses the wrong standard for determining obviousness. The rejection relies upon three different standards in making the rejection:

- 1) "[t]o incorporate such teaching ... would have been obvious;
- 2) [o]ne ... would have expected ... that citrus pectin would be preferred;

and

- 3) one ... would have been motivated to modify ....

However, none of these standards is found in the statute or precedential authority. Because the rejection used the wrong standard, it should be withdrawn for this reason alone.

As set forth above, the rejection based on Schmidt alone is insufficient under § 102 and § 103. And, the Examiner has identified no disclosure in Hill to remedy these fatal factual deficiencies. Indeed, the Examiner relies on Hill solely for its disclosure of a citrus pectin. Because the rejection is factually deficient, it must fail for

this reason also. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). (When a conclusion of obviousness is not based upon facts, it cannot stand.)

As we discussed above, the Examiner has already admitted on the record that Schmidt has at least four factual gaps that prevent it from being cited alone under § 102 or § 103. (See Paper No. 9 at 4.) The Examiner sought to fill these gaps using Newlin, Chiralt, and/or Hussaini. (Paper No. 11 at 4.) In the present Office Action, the rejection base on Schmidt in view of Newlin, Chiralt, and/or Hussaini has been withdrawn. Withdrawal of this rejection is an admission that the Newlin, Chiralt, and Hussaini gap fillers in combination were insufficient to render the claims unpatentable. It stands to reason that Hill alone, which is relied on solely for its disclosure of a citrus pectin, is also insufficient to reject the claims – here claim 25.

We also note that the only active ingredient, or “medicament,” disclosed or exemplified in Hill is acetylsalicylic acid (“aspirin”). Hill does not provide data or technical reasoning to suggest that acetylsalicylic acid would behave in a similar manner as ascorbic acid when combined with pectin. Thus, there is no motivation to combine Hill with Schmidt. For this reason also, the rejection is deficient and should be withdrawn.

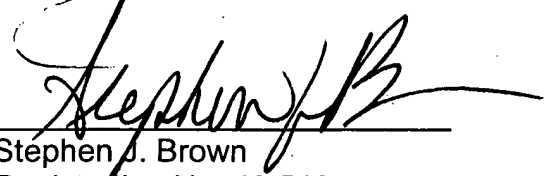
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Reply to Office Action Dated: August 26, 2003

Accordingly, for the reasons set forth above, withdrawal of the rejections and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 26, 2003.

  
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